UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,305	10/31/2003	James Kaput	Kaput-100 US	5444

39843 7590 02/15/2007

BELL & ASSOCIATES
416 FUNSTON ST., SUITE 100
SAN FRANCISCO, CA 94118

EXAMINER	
SISSON, BRADLEY L	
ART UNIT	PAPER NUMBER
1634	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/700,305	KAPUT, JAMES	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *5-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. This application contains claims 5-15, drawn to an invention nonelected with traverse in response received 15 November 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-4 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

> To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of

ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

4. For convenience, claim 1, the only independent claim under consideration on the merits, is reproduced below.

> 1. (Previously Presented) A method for identifying diet-regulated disease-associated polynucleotides comprising the steps of:
>
> (i) selecting at least two different inbred known mammalian genotypes (A and B), one of these genotypes (A) being susceptible to a disease, and the other genotype (B) not susceptible to the same disease;
>
> (ii) dividing each genotype into two groups (A1 and A2 and B1 and B2);
>
> (iii) for each genotype, each group is fed a different diet (A1 is fed diet No.1 and A2 is fed diet No.2, and similarly for B1 and B2);
>
> (iv) measuring gene expression and comparing expression across the strains that differ in either genotype or in diet, but not in both;
>
> (v) analyzing the expression data so as to identify diet-regulated disease-associated genes.

5. For purposes of examination, the claimed method has been interpreted as encompassing the identification of "diet-regulated disease-associated polynucleotides" as found in any life form, be it plant or animal, including humans. In accordance with the claimed method, one is to select "at least two different inbred known genotypes." The specification has not been found to provide an adequate written description of any "two different inbred known genotypes" as they occur in humans, much less any and all other life forms.

6. While one is to identify these polynucleotides on he basis of expression data, the specification fails to provide an adequate written description of how such polynucleotides, even

if expressed differently, are in fact associated with a disease. Further, the specification does not provide an adequate written description as to how one would take into consideration such factors as race, gender, age, medications, radiation therapy, pregnancy, levels of exercise, as well as exposure to chemical or radiation stimuli, in determining whether an individual is "inbred" and/or has gene(s) that are diet-regulated disease-associated as compared to diet-regulated but not disease-associated.

7. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

Accordingly, and in the absence of convincing evidence to the contrary, the specification does not reasonably suggest that applicant was in possession of the invention at the time of filing.

8. The present case is analogous to that presented in Example 18 (pages 65-66) of the Written Description Guidelines (http://www.uspto.gov/web/menu/written.pdf). Unlike the example provided, the claims are not limited to a narrow genus that has been well described, but rather, fairly encompass a vast, if not limitless genus of not only life forms, and associated factors, not the least of which being the vast number of genes, wild type or not, the manner in which the diet is altered, the ability to control for non-tangible factors, e.g., stress. While the

specification asserts that all factors can be and are to be controlled, the specification fails to provide an adequate written description of the broad genera of factors that the claims encompass.

9. When as here, the claims are so broadly drawn, and the specification does not teach an adequate number of embodiments of the genera encompassed, the specification does not reasonably suggest that applicant had possession of the invention at the time of filing.

10. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1-4 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

11. Claims 1-4 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth

> as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

12. It is well settled that one cannot enable that which they do not yet possess. As set forth above, the specification does not provide an adequate written description of the invention so as to reasonably suggest that applicant was in possession of the invention at the time of filing.

The quantity of experimentation necessary,

The amount of experimentation necessary to practice the full scope of the claims is vast, requiring many man-years, if not decades, of trial-and-error research, with little, if any reasonable expectation of success.

The amount of direction or guidance presented,

The specification provides an example whereby possible informative genes are identified in specific murine models. No definitive results are provided which show that the genes are in fact "diet-regulated disease-associated polynucleotides." Further, the specification is silent as to how such a gene, even if identified, is used to achieve a product or result that meets the requirements of utility under 35 USC 101 is obtained.

In order to practice the method of claim 2, for example, one is to compare "the diet-regulated disease-associated genes so identified [in claim 1] with an independently-derived set of diet-regulated and/or disease associated QTLs." The specification does not provide the requisite "independently-derived set of diet-regulated and/or disease associated QTLs" for any and all life forms, such that the comparison can be performed. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. <u>However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art.</u> It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This

> specification provides only a starting point, a direction for further research. (Emphasis added)

The nature of the invention,

The invention relates to search for genes that are associated with why individuals become obese as well as develop other diet-associated diseases, such as diabetes. Clearly, this invention relates directly to matters of physiology and chemistry, which are inherently unpredictable and as such, require greater levels of enablement. As noted in *In re Fisher* 166 USPQ 18 (CCPA, 1970):

> In cases involving predictable factors, such as that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

The state of the prior art,

While various diet studies have been conducted over the years, there is precious little work done in identifying genes that result in the identification of diet-regulated disease-associated polynucleotides.

The breadth of the claims.

The claims fairly encompass the identification of any and all manner of diet-regulated disease-associated polynucleotides in any life form, be it plant or animal, as well as plants that have been transformed so to express animal genes, or animals that have been transformed to express genes found in unrelated animals. The degree to which the polynucleotide is "associated" with diet-

regulated and disease is without limits. Accordingly, genes that are found in a distant cascade of gene function would also be encompassed by the claims.

13. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1-4 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. .

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 1-4 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

16. Claim 1 is indefinite with respect to what constitutes "inbred" genotypes as it relates to any life form, be it plant or animal, including humans. Claims 2-4 and 16, which depend from claim 1, fails to overcome this issue and are similarly rejected.

17. Claim 1 is confusing as it relates to the benchmark to which "more" or "less" are being compared to. Additionally, it is unclear if the difference in susceptibility need be statistically significant.

Response to argument

18. At page 7 of the response received 11 July 2005, hereinafter the response, argument is presented that the specification teaches at paragraphs 70-73 and 83-94 that inbred strains of mice could be used.

19. The above argument has been considered and has not been found persuasive as the claims are not limited to the use of mice, but rather, fairly encompass virtually any life form. It is noted that the preamble of claim 1, the only independent claim under consideration, does not limit the life form being evaluated. While step (i) does refer to "selecting at least two different inbred known mammalian genotypes," the claim does not exclude non-mammalian genotypes, nor limit the source of mammalian genotypes to that of murine systems, nor exclude the correlation of genes in a mammalian system to genes in non-mammalian systems.

20. At page 7, bridging to page 8 of the response to the disclosure not teach of any identified diet-regulated disease-associated polynucleotide, applicant asserts that this is the intent of the claimed invention.

21. The above argument has been fully considered and has not been found persuasive. While the invention is to arrive at the discovery of such polynucleotides, the specification must provide an adequate written description of such method and how to recognize the polynucleotide so identified. Also, in order to satisfy the enablement requirement, the specification must also set forth a reproducible method by which the polynucleotide so identified is used in a method that meets the utility requirements under 35 USC 101. As set forth in the requirements of 35 USC 112, first paragraph, the specification must teach how to make and how to use the invention. A review of the original disclosure and of the remarks found in the response fails to identify just where the full, concise and exact disclosure of the invention is to be found so that it is not only fully enable, but also described in terms that reasonably suggest that applicant had possession of the invention at the time of filing.

22. At page 8 of the response argument is presented "that the only variable being examined between the two species is diet and disease susceptibility."

23. This argument has not been found persuasive, as the claims are not limited to mice, but fairly encompasses humans. Indeed, as the genetic makeup of the human is known, then too is the knowledge of their genotype. Accordingly, the specification is silent as to how one is to control for variables such as race, age and sex. Clearly, the aspect of age is not considered even if using the murine model of the application. Even if the claims were to be limited to the use of a specific animal model, the specification is silent as to the genes of any one of these model being an art-accepted model for any of the specific genes in any other life form.

24. At page 8, bridging to page 9 of the response argument is presented that QTLs are not part of the invention and that claim 1, for example, is not limited to QTL comparison.

25. This argument has not been found persuasive for an independent claim must encompass that recited in the independent claims. Accordingly, with claim 2 reciting such limitation, claim 1 must encompass it. It is essential that the specification provide an adequate written description of the method, including the reagents and steps to be performed in using same. Claim 2 explicitly requires on to compare "diet-regulated disease-associated genes so identified with an independently-derived set of diet-regulated and/or disease associated QTLs." Clearly, these are essential to practicing the claimed method, yet the specification is silent as to just what they are or how they are to be obtained in a reproducible manner. In short, applicant has not provided the requisite starting materials.

26. At page 9 of the response argument is presented as to what the definition of "inbred" is, indicating that such is achieved in mice at F_{20}.

27. This argument has not been found persuasive as the claims are not limited to mice and no evidence has been presented as to how this would be applied to other life forms, including humans.

28. At page 9 of the response argument is presented as to what one of skill in the art would have known.

29. This argument has been fully considered and has not been found persuasive. Attention is directed to MPEP 2145.

> Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art.
> The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

30. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1-4 and 16 remain rejected under 35 USC 112, first and second paragraphs.

Conclusion

31. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

32. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

34. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

35. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

B. L Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS